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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,454

09/17/2003

Mark L. Jenson

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3774

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,454	<b>Applicant(s)</b> JENSON, MARK L.	
	<b>Examiner</b> ANN SCHILLINGER	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 19, 20, 22, 26, 27 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 19, 20, 22, 26, 27 and 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 4 is objected to because of the following informalities: it does not give a reference point from which the oblique angle of the first liner is measured. Claim 10 is objected to because of the following informalities: it does not clearly indicate if the “foreign body” and the stent located between the two liners are the same element. Appropriate correction is required.

Claim 5 recites the limitation "side segment surfaces" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 13, 14, 27, 48, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. (US Pat. No. 6,149,681) in view of DiMatteo et al. (US Pat. No. 6,440,164) further in view of Banas et al. (US Pat. No. 6,124,523). Houser et al. discloses the following of the claimed invention as shown in Figure 42: a composite device for delivery of bioactive agents associated therewith to a site of implantation of said device comprising: a first polymeric liner (inner element 246); a second polymeric liner (outer element 246); an intermediate structural member or elongate stent (258) interposed between said first and said second polymeric liners, creating opposite smooth and uneven surfaces, said intermediate structural member being defined by solid segments and openings therebetween such that the first

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liner is bonded to the second liner through said openings to form at least one pocket adjacent to said solid segments, said pocket being defined by said first and second liners, their area of direct bonding, and said solid segments; and a fluid containing a bioactive agent disposed within said pocket adjacent to said solid segments of said intermediate structural member (col. 3, lines 41-52). The first and the second liners are adheringly joined at a location substantially co-extensive with said inner surface of said tubular body (please see Fig. 42 which shows the boundaries of the inner surface and the location where the first and the second liners are joined as being substantially coincident within the same space).

Houser et al. further discloses the limitations of claims 13-15 in col. 7, lines 50-58. With respect to the choice of a trapezoidal cross-section, applicant's specification fails to establish a showing of criticality for the particular design. Therefore, it would have been an obvious matter of design choice to use a solid segment with a trapezoidal cross-section as such a modification would have involved a mere change in the shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art.

Houser et al. does not disclose the first liner being bioabsorbable and the second liner being made from ePTFE. DiMatteo et al. teaches an implantable stent and prosthetic valve that includes a bioabsorbable liner and a liner made from ePTFE in col. 10, lines 10-38, col. 11, lines 36-53, and col. 13, lines 50-65 for the purpose of utilizing the materials' biocompatibility and facilitating the release of the drugs the stent is carrying. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the liners of Houser et al. to be constructed from ePTFE and a bioabsorbable material in order to utilize the materials' biocompatibility facilitating the release of the drugs the stent is carrying.

Houser et al. and DiMatteo et al. teach the claimed invention, however, they do not teach the ePTFE material having an internodal distance range of about 5 to 10 microns. Banas et al. teaches a stent with an ePTFE layer having an internodal distance of about 10 microns in col. 13, lines 31-47 for the purpose of providing the ePTFE layer with greater physical strength. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ePTFE layer with greater physical strength.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of DiMatteo et al. and Banas et al., further in view of Rudakov et al. (US Pat. No. 6,451,050). Houser et al., as modified by DiMatteo et al. and Banas et al., discloses the invention substantially as claimed, however, they do not teach encapsulating a bioactive agent in a polymeric matrix. Rudakov et al. teaches a stent where the bioactive agent is encapsulated in a polymeric matrix in col. 4, lines 40-50 for the purpose of controlling the release of the bioactive agents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use microparticles in the matrix in order to controlling the release of the bioactive agents.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of DiMatteo et al., Banas et al., and Rudakov et al., as shown in claim 11, further in view of Helmus et al. (US Pub. No. 2002/0032477). Houser et al., as modified by DiMatteo et al., Banas et al., and Rudakov et al., discloses the invention substantially as claimed, however, they do not teach constructing the polymeric matrix holding the bioactive agent of microparticles. Helmus et al. teaches a biological prosthesis that uses microparticles in the matrix in paragraph 0048 for the purpose of controlling the release of the bioactive agents. Therefore, it would have been obvious

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to one of ordinary skill in the art at the time the invention was made to use microparticles in the matrix in order to controlling the release of the bioactive agents.

Claims 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of DiMatteo et al. and Banas et al., further in view of Golds et al. (US Pat. No. 6,001,125). Houser et al., as modified by DiMatteo et al. and Banas et al., discloses the invention substantially as claimed, however, they do not teach using porous ePTFE to construct the device. Golds et al. teaches a vascular graft constructed from porous ePTFE in columns 3 and 4 for the purpose of utilizing the material's enhanced radial strength of the less porous area and the enhanced cell endothelialization associated with the more porous area. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use porous ePTFE in order to utilize the material's radial strength and cell endothelialization.

Claim 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of DiMatteo et al. and Banas et al., further in view of Rhodes (US Pat. No. 5,665,117). Houser et al., as modified by DiMatteo et al. and Banas et al., discloses the invention substantially as claimed, however, they do not teach using stainless steel or tantalum to construct the device. Rhodes teaches a biological prosthesis that uses stainless steel or tantalum to construct the device in col. 6, lines 8-30 for the purpose of utilizing the material's biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use stainless steel or tantalum to construct the device in order to utilize the material's biocompatibility.

Claims 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al., as modified by DiMatteo et al. and Banas et al., in view of Yang (US Pub. No.

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2002/0062147). Houser et al., as modified by DiMatteo et al. and Banas et al., discloses the invention substantially as claimed, however, they do not teach using a gel to contain the bioactive agent. Yang teaches a biological prosthesis that uses a gel to contain the biological agent in paragraph 0073 for the purpose of retaining the drug in the device for a longer period of time. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a gel to contain the bioactive agent in order to retain the drug in the device for a longer period of time.

### ***Response to Arguments***

Applicant's arguments, with respect to the new matter objections and rejections drawn to the Applicant's device having smooth and uneven surfaces, filed 10/22/2009 have been fully considered and are persuasive. These rejections and objections have been withdrawn.

Applicant's remaining arguments filed 10/22/2009 have been fully considered but they are not persuasive. The Applicant contends that the Houser and the DiMatteo references do not teach pre-treating the pocket of the device with a surfactant. This claim language is directed towards the manner in which the device is constructed. Claim language addressing the manner in which a device is constructed is not germane to the patentability of the device itself.

Therefore, this language has not been given patentable weight.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

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Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774